Office Action Summary	Application No.	Applicant(s)	
	09/767,421	SHAMBLOTT ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 2, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,9-13,15,22-32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,9-13,15,22-32 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *January 22, 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive. Claims 1, 9-13, 15, 6, 22-32 and 34-38 are pending.

The term "EBD-derived cell" means an undifferentiated cell that composes an embryoid body.

The rejection under 35 U.S.C. § 112, first paragraph as lacking written description made in the office action mailed February 15, 2007 is withdrawn in view of applicant's response.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9-13, 15, 16, 22-32 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 22 and 38 contain language not supported by the specification. The claims state "adhesion to a defined substrate lacking a feeder layer." A review of the specification, with emphasis on the particular paragraphs indicated by applicant does not convey that at the time of the present invention, applicant had possession of the claimed invention. The specification discloses growth of embryoid body cells on a substrate in the absence of feeder cells, but makes no reference to the substrate being "defined" (specification, page 53, lines 8-10). The closest mention of "defined" with regards to the culture of EBD cells is "defined extracellular matrix components" (page 22, lines 20-23).

Applicant provides citations in the specification that support the phrase "adhesion to a defined substrate lacking a feeder layer." This is not persuasive.

In the citation on page 6 of the response filed July 2, 2007, the specification states "attachment substrates" include "viable cell feeder layers." Thus, the specification clear states one type of attachment substrates is a feeder layer. While the additional citations mention specific substrates contemplated: bovine collagen I and human extracellular matrix (response, page 8); and matrigel and fibronectin (response, page 9), the contemplation of a defined substrate lacking a feeder layer is not supported by any of these disclosures. Further, the disclosure of "define substrate" and "three-dimensional architecture required" also do not provide evidence of such contemplation, as there is no disclosure of "lacking a feeder layer." Thus, since a feeder layer as an attachment substrate is clearly contemplated, and there is no disclosure of a defined substrate not being a feeder layer, this limitation to claims 1, 22 and 38 lacks written description. This particular situation is seen as overcoming the finding in Fujikawa that exact language isn't required. Further, the issue isn't if the skilled artisan would regard a defined substrate as including an extracellular matrix, but if applicant convey a define substrate lacking feeder cells. There is no evidence in the response that a skilled artisan would reasonably understand a define substrate to lack feeder cells necessarily.

A chemically define substrate, such as in applicant's submitted art of Aria, is a defined substrate, but the claims are broadly to a defined substrate lacking feeder cells. It is the entire concept of "defined substrate lacking feeder cells" for which there is no figurative or literal support in the specification.

Claims 1, 9-13, 15, 6, 22-32 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable a use for EBD cells lacking telomerase activity that is senescent cells. The uses disclosed in the specification each require the cells to actively divide. Senescent cells are not going to be useful for cell culture, tissue transplantation, tissue engineering, drug discovery or gene therapy. A senescent cell has quit dividing. Each disclosed use requires that the cells divide.

Applicant argues senescent cells can be used for transplantation and provides Ostenfeld as evidence. Applicant argues Ostenfeld teaches human neuronal precursor cells express very low levels of telomerase at early passage that decreases to undectable levels, the cells when implanted continued fiber outgrowth and that for the treatment of Parkinson's disease these cells afford a good safety profile. These arguments are not persuasive.

The claims are not limited to treatment of Parkinson's disease, so applicant is arguing a limitation not in the claims. Further, the cells of Ostenfeld are neural precursor cells, whereas the presently claimed cells are cells isolated from embryoid bodies, and as such are not neural precursor cells. Thus, the cells of Ostenfeld are not comparable developmentally with those claimed. It is noted, the implanted cells of Ostenfeld are taught to under go rapid proliferation immediately post-transplantation, and indication that they had not senesced. Further, as the cells did senesce, they failed to product tyrosine hydroxylase. The reason for cell therapies in Parkinson's disease would be to provide tyrosine hydroxylase producing cells for the production of L-DOPA. Further, Olstenfeld states the cells need to have the dopaminergic phenotype prior to transplantation. A full reading of the abstract indicates the cells as described are not useful for treatment, but may be once the dopaminergic phenotype is induced. Thus, the senesced cells of Olstenfeld are not useful

as argued. For differentiation, cell division is required. As disclosed in the specification, EBD cell cultures lacking telomerase are senescent, and senescent cells lack cellular division (specification, page 77, lines 4-5 and 12-14). Thus, the claimed cells lack a patentable use.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-13, 15, 6, 22-32 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to EBD cells, which lack telomerase activity or senescent EBD cells. This is confusing because the specification teaches cells undergoing more than 70 population doubling, clearly an indicator of telomerase activity (page 64, lines 16-18.) From the disclosure as a whole, the invention does not seem to senescent cells, but cells that are embryonic and proliferative.

This rejection was not addressed in the response of July 2, 2007. To the extent that the above argument applies, there are repeated here.

The claims are free of the prior art. At the time of the instant invention, the prior did not teach or suggest a human EBD that lacked telomerase activity.

It is noted that Hogan, of record, teaches human EBD cells and methods of making them. However, Hogan's cells are actively dividing. Should applicant amendment the claims, deleting "lacking telomerase" activity, the Hogan reference or other references will be used to rejection the claims under 35 U.S.C. § 102, 103 or 102/103. At this point, the only claims potentially available to applicant would be methods of obtaining EBD cells if the claims were appropriately limited away from Hogan. The human EBD cells of Hogan are seen as

anticipating the presently claimed cells. The examiner has no suggestions at this point to forward the cell claims to allowance.

As always, applicant's representative is invited to call the examiner to discuss the rejections present or past so that resolution can be obtained.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

September 18, 2007